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(71) Applicant *(for all designated States except US)*: FLYING NULL LIMITED [GB/GB]; Harston Mill, Harston, Cambridge CB2 5NH (GB).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: ENGLAND, Mark [GB/GB]; 44a Bitt Lane, Milton, Cambridge CB4 6DG (GB). DAMES, Andrew, Nicholas [GB/GB]; 74 De Freville Avenue, Cambridge CB4 1HU (GB). CROSSFIELD, Michael, David [GB/GB]; Perne Drift, Burton End, West Wickham, Cambridge CB1 6SD (GB).

(74) Agent: ABRAMS, Michael, John; Haseltine Lake & Co., Imperial House, 15–19 Kingsway, London WC2B 6UD (GB).

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(57) Abstract

A surgical device, e.g. a catheter or a prosthesis, is disclosed which is characterized in that it carries, at a predetermined location, a tag formed of a high permeability, low coercivity magnetic material. Also disclosed is a method of locating a surgical device within the human or animal body, which comprises inserting the device into the body together with a magnetically active marker, the marker being associated with a predetermined location on the surgical device; and sensing the position of the marker, and hence of the surgical device, by remotely detecting its magnetic response to an interrogating signal. Systems for use in this method are also disclosed.

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IMPROVEMENTS RELATING TO SURGICAL DEVICES AND THEIR LOCATION

This invention relates to the location of surgical devices within the human or animal body and, more particularly, is concerned with such systems using magnetic principles.

The invention is of particular benefit as applied to catheter location, but is not limited to this field of application; it may also, for example, find application in the locating of prostheses, needles, ports and other surgical devices which may deliberately or accidentally enter the human or animal body.

The magnetic principles used in this invention are those suitable for remote detection of a small magnetic marker. A preferred detection system is that based on Flying Null technology; this technology is described, for example, in our PCT Patent Publication No. WO 96/31790.

According to one aspect of the present invention, there is provided a method of locating a surgical device within the human or animal body, which comprises inserting the device into the body together with a magnetically active marker, the marker being associated with a predetermined location on the surgical device; and sensing the position of the marker, and hence of the surgical device, by remotely detecting its magnetic response to an interrogating signal.

As indicated above,this method is very useful when the surgical device in question is a catheter. In such a case, the marker is advantageously located close

to the tip of the catheter (i.e. that end of the catheter which first enters the body). The marker may be provided on a surface of the catheter itself, or it may be provided on a guide wire used during insertion of the catheter.

The nature of the marker will be selected according to the specific circumstances of its intended use; it will, however, generally be formed from a high permeability, low coercivity magnetic material. Typically, the marker will be in the form of a thin film, a wire or a strip.

According to a second aspect of the present invention, there is provided a surgical device, e.g. a catheter or a prosthesis, which is characterised in that it carries, at a predetermined location, a tag formed of a high permeability, low coercivity magnetic material. The tag can be very small and therefore does not interfere with the operation of the surgical device.

According to a third aspect of the present invention, there is provided a system for use in determining the location of a surgical device within the human or animal body, which system comprises a surgical device which carries, at a predetermined location, a tag formed of a high permeability, low coercivity magnetic material; means for generating a rotating magnetic field; and means for detecting the interaction between the tag and the rotating magnetic field.

While the invention has relatively wide applicability in surgical procedures, it will be described hereafter in relation to one embodiment,

namely the location of catheters.

The use of catheters for drug delivery and other medical/surgical procedures is increasing. Typically, catheters are inserted via a major blood vessel in the leg or arm of the patient. This is conventionally done by inserting a guide wire into the selected blood vessel, and passing the catheter over the wire in the manner of a sheath. Once the catheter is inserted, the surgeon has to ensure that it reaches the desired site of action. This is conventionally achieved by attaching a coil set to the wire over which the catheter is carried, and then sensing the location of the coil. This requires an electrical connection between the coil set within the patient's body and the exterior.

The current generation of catheter location systems use a hand-held receiver unit, connected to an active marker on the catheter by a cable. The receiver is swept over the area of the body where the end of catheter is expected to be, and an audible indication of proximity is given, together with a visual indication of the direction that the catheter is pointing in. As the receiver passes over the plane of the tag, an audible beep is heard.

Furthermore, once the catheter is correctly positioned, with its tip at the desired site of action, the locating wire (with the coil set which it carries) is withdrawn from the patient, leaving the catheter in place. After withdrawal of the coil set, it is only possible to determine the location of the catheter by x-ray, assuming that it has been treated with an x-ray opaque coating or marker. Otherwise , the surgeon is left to assume there has been no movement of the

catheter during or after withdrawal of the wire. This assumption, at best, is unreliable and may, in critical applications, be dangerous.

According to a fourth aspect of the present invention, there is provided a catheter which is characterised in that it carries, at or close to its tip, a tag formed of a high permeability magnetic material. The tag can be very small and does not interfere with the catheter's operation.

According to a fifth aspect of the present invention, there is provided a catheter location system which comprises a catheter which carries, at or close to its tip, a tag formed of a high permeability magnetic material; means for generating a rotating magnetic field; and means for detecting the interaction between the tag and the rotating magnetic field.

In the present invention, the tag is made from a high permeability magnetic material (such as those described elsewhere for making tags for Flying Null systems). No electrical connection is required, which is a major advantage, since there are no connecting wires to get in the way of the surgeon, and the ability to sterilise the catheter is not affected by the presence of the tag. All the other functionality of the existing catheter location systems can be implemented.

In the description which follows, the invention will be described in relation to one specific embodiment. The system uses proprietary Flying Null technology, based on the existing Flying Null Reader electronics, to determine the position and orientation of the tag. The accompanying drawings are, briefly, as

follows:

Figure 1 illustrates the basis of operation of the catheter location system;

Figure 2 is a block diagram of the components of the system;

Figure 3 illustrates one advantageous configuration for the receive coil in the detection apparatus;

Figure 4 illustrates the operation of an orientation-determining technique;

Figure 5 illustrates the placement of a catheter in the body of a human patient;

Figure 6 illustrates an alternative receiver coil arrangement to that of Figure 3; and

Figure 7 demonstrates the effect on the receive coils' response by the incorporation of one of the coil components.

The operation of this system is best understood by first considering a much simpler system with a set of coils similar to those in the Flying Null loop reader antenna (see International Patent Publication No. WO 97/48890, especially Figure 2 and the description thereof), but additionally with a DC bias field in the plane of the coil. If a tag is placed in the centre of the loop and rotated about its mid-point in and out of the plane of the coil, the received signal in the single receiver coil will be a series of "blips", corresponding to the points when the tag is orthogonal

to the bias field. i.e. the points where the tag rotates through the null plane of the system. This is illustrated in Fig. 1.

In the frame of reference of the tag, the loop antenna (which has a 6.37 kHz transmit field) and the DC bias field appear to be rotating. If the rotational position of the bias field is known as a function of time, then measurement of the time at which the blip occurs can be used to calculate the direction of the tag. This is the basis of operation of the catheter location system. Rather than spinning the coil and bias magnet, the rotation bias (i.e. LF) and HF drive fields are preferably generated by two orthogonal sets of coils. The waveforms to these coils preferably consist of a sinusoidal low frequency (LF) component onto which is superimposed an HF component whose envelope is equal to the LF signal, shifted in phase by 90 degrees.

The spinning receiver coil is again preferably synthesised from a pair of orthogonal coils, whose outputs are combined with sine and cosine weights to generate a single receive channel output.

The prototype system was constructed using two circuit boards of the type used in several Flying Null applications. These boards contain a receiver band-pass filter and low noise amplifier, a microprocessor with integral multi-input analogue to digital convertor, and a power amplifier. Board 1 is configured as a 2-channel reader, whilst board 2 is used as the basis for a waveform generator. For convenience, these will be referred to as FN boards.

The transmit coils in this example are a pair of

simple, orthogonal solenoids wound on a rectangular former, with 120 turns of 0.6 mm copper wire. The windings are distributed with a bias towards the edges of the former.

In one version of the system, the receive coils each consist of two trapezoidal coils, wound in opposite directions, such that the combined inductance is equal to 3 mH (about 150 turns of wire). (See Figure 3).

Other coil arrangements are also possible, in particular with the receivers wound as two stacked solenoids; with an arrangement of this sort, each solenoid of the receiver is preferably half the thickness of the transmit coil. The main benefits of balanced coil configurations are to minimise direct coupling between the transmitter and the receiver and to provide rejection of far-field interference signals.

The positional resolution of the system along one axis can be improved by using a magnet to generate a static gradient field beneath the receive antenna array. For convenience, the magnet can be attached to the antenna. The magnet may be a simple permanent magnet or an electromagnet.

Figure 6 shows a currently preferred arrangement for the receiver coils in a system of this invention. The arrangement includes a third coil which provides signals which can be used to provide enhanced positional resolution. For clarity, it is to be noted that only one balanced coil set is shown. In the complete system, a further set of receiver coils is required, these being wound over the tops of the solenoids 61 and 62, with their winding directions at

90 degrees to those of solenoids 61 and 62. This construction may be used as an alternative to adding the gradient magnet described above. The rotational unambiguity of the system is not sacrificed with this construction, which otherwise can be described as comprising a pair of stacked solenoids 61 and 62, each of which is of identical construction, together with an additional receiver coil 63 wound around the periphery of the existing coil set. Coil 63 consists in this embodiment of 50 turns of 0.25mm copper wire. Its maximum output is generated when a magnetic tag (illustrated as 64 in Fig. 6) is lying in a plane parallel to that of the coil 63 and orthogonal to the winding and directly beneath the winding. No signal will be coupled into the coil from the same tag when it passes beneath the centre of the coil. Thus as a tag passes beneath this receiver arrangement, the signal received in coil 63 will first build up to a positive peak and then decrease, passing through zero to a negative peak and then tending again towards zero.

The outputs from "original" antenna 61 and 62 and the orthogonal balanced coil set not shown in Figure 6 are processed separately from that of coil 63. This processing requires additional circuitry not indicated in Figure 2.

This response pattern of the additional coil 63 is illustrated by curve 70 in Fig. 7. By comparison, the output obtained by a receiver arrangement consisting of solenoids 61 and 62 but without coil 63 is shown by curve 71. The position of the null 72 corresponds to the point where the tag is positioned directly below the centre of the coil 63; this null point can be detected with greater precision than the position of the maximum 73 of curve 71. This is because the change

in signal amplitude with change in tag position is greatest in coil 63 at the null point 72 of curve 70, whereas it is at its smallest in the case of point 73 on curve 71. This can be exploited in a simple processing algorithm which, for example, detects the occurrence of a zero-crossing signal in the additional channel (output from coil 63) when there is a signal above a predetermined threshold in the original receiver channel (i.e. output from 61 and 62 or the orthogonal balanced coil set making up the complete receiver coil array). This allows an enhancement of tag position measurement accuracy without any significant additional weight and cost.

To improve rejection of far-field interference, the coil 63 may be formed as a balanced quadruple. This could be achieved by using two simple loops connected in series and wound in ant-phase around the top and bottom of the assembly 61, 62.

A currently preferred form of construction for tag 64 comprises an element of dimensions 30mm x 0.5mm x 20 microns formed of Vacuumschmeltze 6025 spin melt ribbon. This is preferably used together with an overlaid bias element which may, for example, be of the dimensions 40mm x 0.75mm x 50 microns and may be formed of Arnokrome (Br 1.15T), fully magnetised.

The following describes the details of a prototype system. This system does not include the additional coil 63 described above for enhancing tag position measurement accuracy. The waveform generator is driven by one of the two 80552 microcontrollers. It has two 16-bit DACs which are updated at about 25 kHz. The waveforms are first generated and stored in an array. The contents of the array are then clocked out to the

DAC's to generate the waveforms. The DAC's are double-buffered, so that the data can be entered asynchronously, but the new values can be latched simultaneously and synchronously for both channels using a hardware clock. Two RC filters are used on each output to remove the higher harmonics. Each time the array cycles round, a short pulse is generated which is used to synchronise the waveform generator with the second FN board (see below).

The waveforms are generated using equations of the form:

$$x_n = LF.\sin\{2\pi n/N + p\} + HF.\cos\{2\pi n/N\}.\sin\{2\pi n/4 + ph1\}$$

$$y_n = LF.\cos\{2\pi n/N + p\} - HF.\sin\{2\pi n/N\}.\sin\{2\pi n/4 + ph2\}$$

A 160w MOSFET stereo power amplifier was chosen to drive the coils. This was the simplest method to integrate suitable power amplifiers and their power supply into a single box. The filter consists of a high-Q parallel resonant circuit (resonant at 12.744 Khz, i.e. at the second harmonic frequency) in series with the transmit coil. The transmit coil also forms part of a parallel resonant circuit at 6.37 kHz.

The two sets of orthogonal balanced coil sets are connected to the two sets of receiver coils. The boards are synchronised together by coupling the 12.744 kHz detection signal from the waveform generator board to the second board.

The second FN board forms the basis of the receive coil synthesizer. Both receivers are sampled at a rate of 3.186 kHz. The least significant 2 bits of the 10

bit result can be discarded because to reduce processing time.

Initially, the system samples background values, and stores these in an array. This array is indexed by the sample number since the last synchronisation pulse. A total of 192 samples are expected between each sync pulse from the waveform generator.

Once a set of background values has been acquired, the system enters normal operation. In this mode, the indexed background value is initially subtracted from the incoming receiver values. After limiting the values to prevent later maths overflow, each channel is then multiplied by either cos (channel 1(R)) or sin (channel 2 (L)) of the rotation angle, and in operation the results are added together to generate the final synthesized receive signal. This is output in real time via a PWM for display on an oscilloscope.

A peak and zero-crossing detection algorithm adapted from the original FN tag decoding system is used to determine where peaks occur. The polarity of the recovered signals is always the same (i.e. the negative peak is always first). Rather than determining the time at which the mid-point between the peak and the trough occurs (as in the FN tag reader), the system picks the point at which the signal crosses through zero from the negative direction.

For each complete cycle (i.e. one revolution of the LF field), two zero crossings should be detected. In the absence of any external fields, these should be exactly equally spaced in time (as illustrated in Fig. 1). When a DC field is present along the tag, the times at which the net gradient along the tag is zero

are no longer equally spaced, and an asymmetry occurs in the timing of the zero crossings (see Fig. 4). This asymmetry is used to resolve the 180 degree ambiguity over the direction of the tag. The direction is calculated from the time which is exactly in the centre of the shorter of the two gaps. This information is converted and fed to a set of 8 LED's to indicate the angle.

An audible indication of the proximity of the tag is generated by feeding information on the amplitude of the signal via a PWM output to a voltage-to-frequency converter, which drives a small speaker. A similar arrangement may be used to drive the AGC proposed in the modification mentioned below.

The amplitude information is differentiated to determine the point of closest approach to the tag. When this is detected, an audible beep is generated.

The dynamic range, and hence the range over which the tag reader will operate, can be extended by implementing a simple AGC. The receiver board generates a signal (the AGC voltage) which sets the overall amplitude of the waveform generator. Initially, this is set at its maximum value, but if the input to the receiver begins to overload, the AGC voltage is reduced in steps until the receiver signal is the correct amplitude. As the background level depends on the waveform generator drive level, the system captures background signals for a number of different drive levels before tag detection begins.

With large bias fields on the tag, the familiar symmetric tag signal becomes distorted into a simple peak. The detection algorithm can be modified to

accept this signal instead, following the use of larger bias fields and reducing any possibility of the ambiguity of tag direction.

In operation, the antenna coil is manually scanned across the region containing the tag. When the tag is near enough, the warble tone will be heard, and the LED closest to the correct direction will illuminate. The warble tone indicates proximity to the tag by its pitch.

The LED's indicate direction. The LED display will track the tag direction, unambiguously, over a full 360 degrees.

The transmit coils in the embodiment just described were as follows:

Size	132 mm x 132 mm x 53 mm high
Turns	120 turns of 0.6 mm wire
Inductance	863 μH
Resistance	3.45 Ω
Q @ 6.37 kHz	10
LF current	3.1 A peak (cold)
	3.0 A peak (warm)
HF current	3.5A peak-peak (warm)
LF dipole moment	2.52 Am^2
HF dipole moment	1.47 Am^2
Power dissipation	31.5 w (LF)
	7.6 W (HF)
	39 W total for whole antenna

and the receive coils had the following characteristics:

Inductance	3.15 mH
Q	9.4 @ 10 kHz

Quadruple moment	0.048 Am^3

The performance of the system is as follows:

Detection range:	150 mm for 30 mm long tag
Angular resolution:	2 degrees
Angular display	nearest 22½ degrees

While the invention has been described with specific reference to certain embodiments thereof, it will be apparent to those of ordinary skill in the art that it may be used in a variety of circumstances other than those described herein. Such additional uses form part of this invention, as defined in the appended claims.

Referring to Figure 5, a catheter in accordance with this invention may be inserted into a vein as at 50 and then be guided to the site where drug delivery is required - in this illustration, to the heart. The system described above may be used to determine progress of the catheter towards the heart, giving information about its direction at any given time as required, and also enabling the final positioning of the catheter tip to be achieved with great accuracy.

CLAIMS:

1. A method of locating a surgical device within the human or animal body, which comprises inserting the device into the body together with a magnetically active marker, the marker being associated with a predetermined location on the surgical device; and sensing the position of the marker, and hence of the surgical device, by remotely detecting its magnetic response to an interrogating signal.

2. A method according to claim 1, wherein said surgical device is a catheter.

3. A method according to claim 2, wherein said marker is located close to the tip of the catheter (i.e. that end of the catheter which first enters the body).

4. A method according to claim 2 or 3, wherein the marker is provided on a guide wire used during insertion of the catheter.

5. A method according to claim 1, 2, 3 or 4, wherein said marker is in the form of a thin film, a wire or a strip.

6. A method according to claim 1, wherein said surgical device is a prosthesis.

7. A surgical device, e.g. a catheter or a prosthesis, which is characterised in that it carries, at a predetermined location, a tag formed of a high permeability, low coercivity magnetic material.

8. A system for use in determining the location

of a surgical device within the human or animal body, which system comprises:

(i) a surgical device which carries, at a predetermined location, a tag formed of a high permeability, low coercivity magnetic material;

(ii) means for generating a magnetic field; and

(iii) means for detecting the interaction between the tag and the magnetic field.

9. A system as claimed in claim 8, wherein said means for generating a magnetic field is arranged to generate a rotating magnetic field.

10. A system as claimed in claim 9, wherein the system comprises a pair of orthogonally arranged solenoids which function as transmit coils, the waveforms fed to the solenoids (x and y) being arranged to synthesise a rotating magnetic field.

11. A system as claimed in claim 10, wherein said transmit coils are supplied with waveforms comprising a sinusoidal low frequency signal component onto which is superimposed a high frequency signal component whose envelope is equal to the low frequency signal but shifted in phase by 90 degrees.

12. A system as claimed in claim 10, which comprises a receiver arrangement in the form of a pair of orthogonal coils whose outputs are combined with sine and cosine weightings to generate a single receive output.

Fig.1.

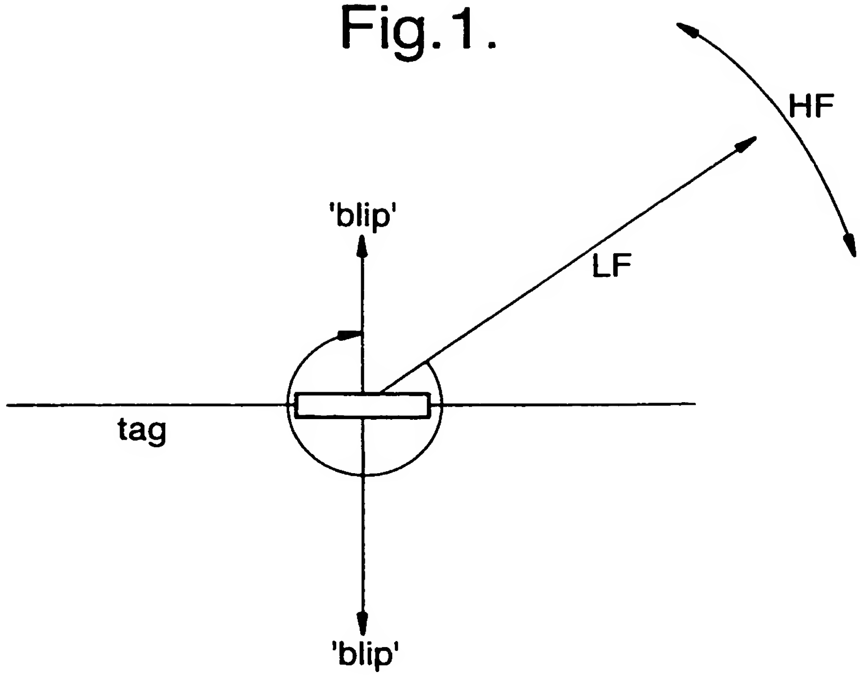

HF
LF
'blip'
tag
'blip'

Fig.2.

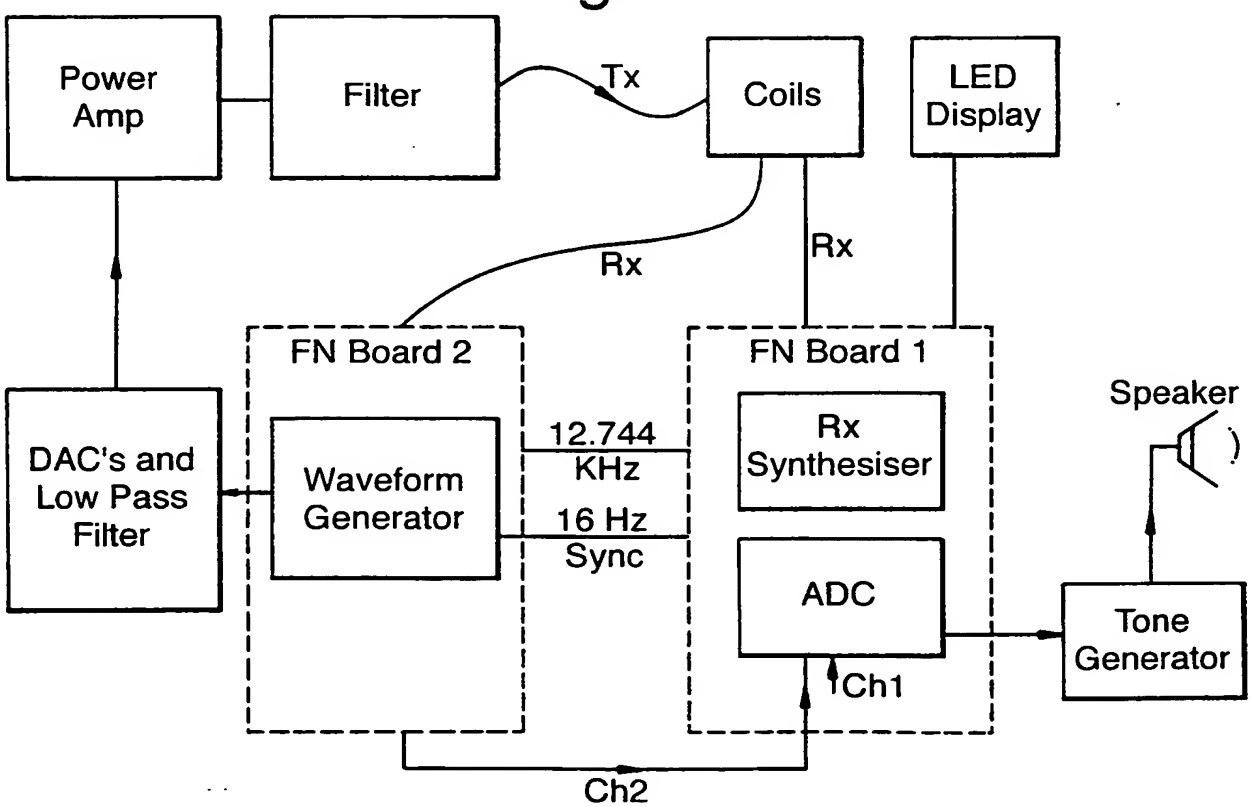

Power Amp
Filter
Tx
Coils
LED Display
Rx
Rx
FN Board 2
FN Board 1
Waveform Generator
Rx Synthesiser
12.744 KHz
16 Hz Sync
DAC's and Low Pass Filter
ADC
Ch1
Speaker
Tone Generator
Ch2

Fig.3.

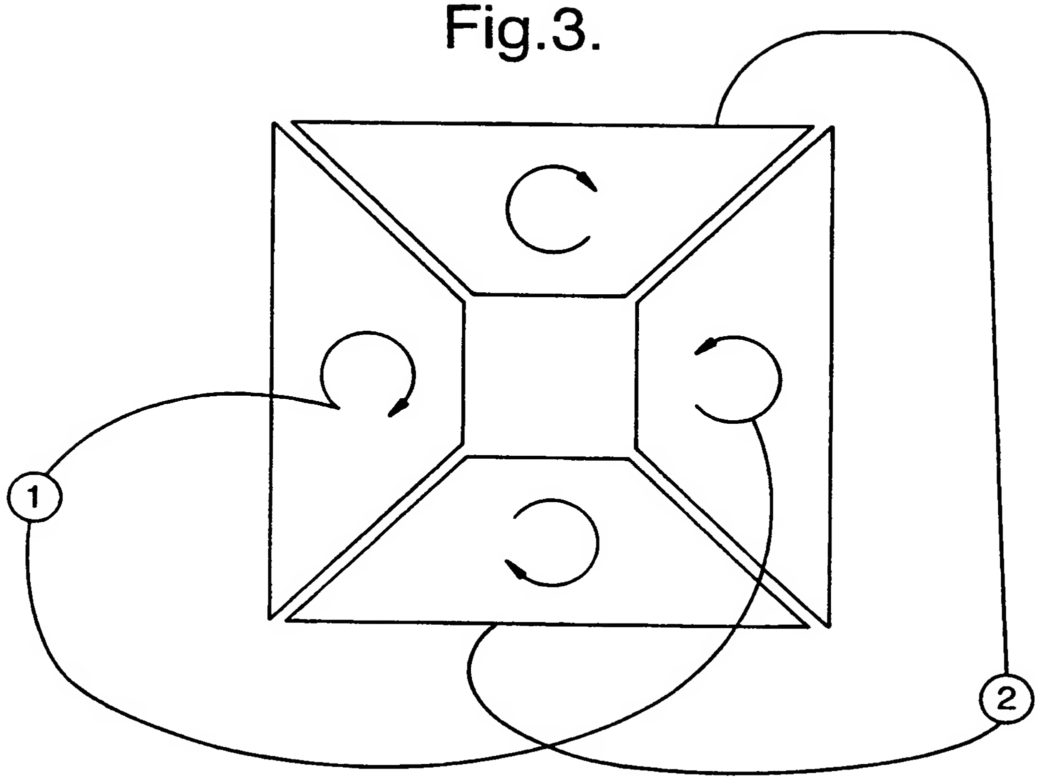


Fig.4.

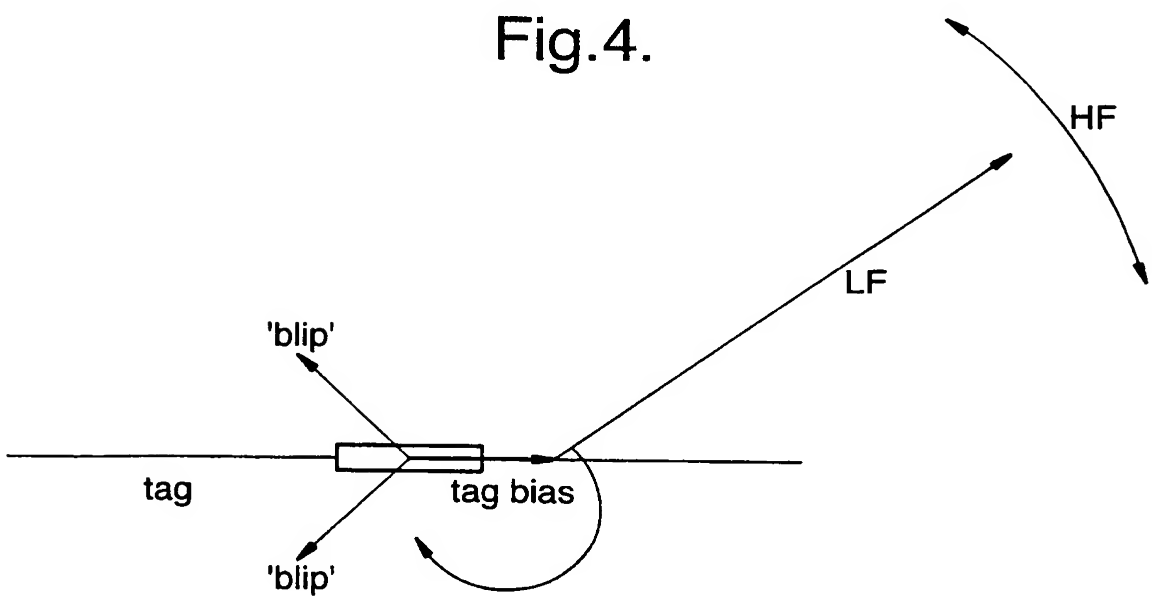


Fig.5.

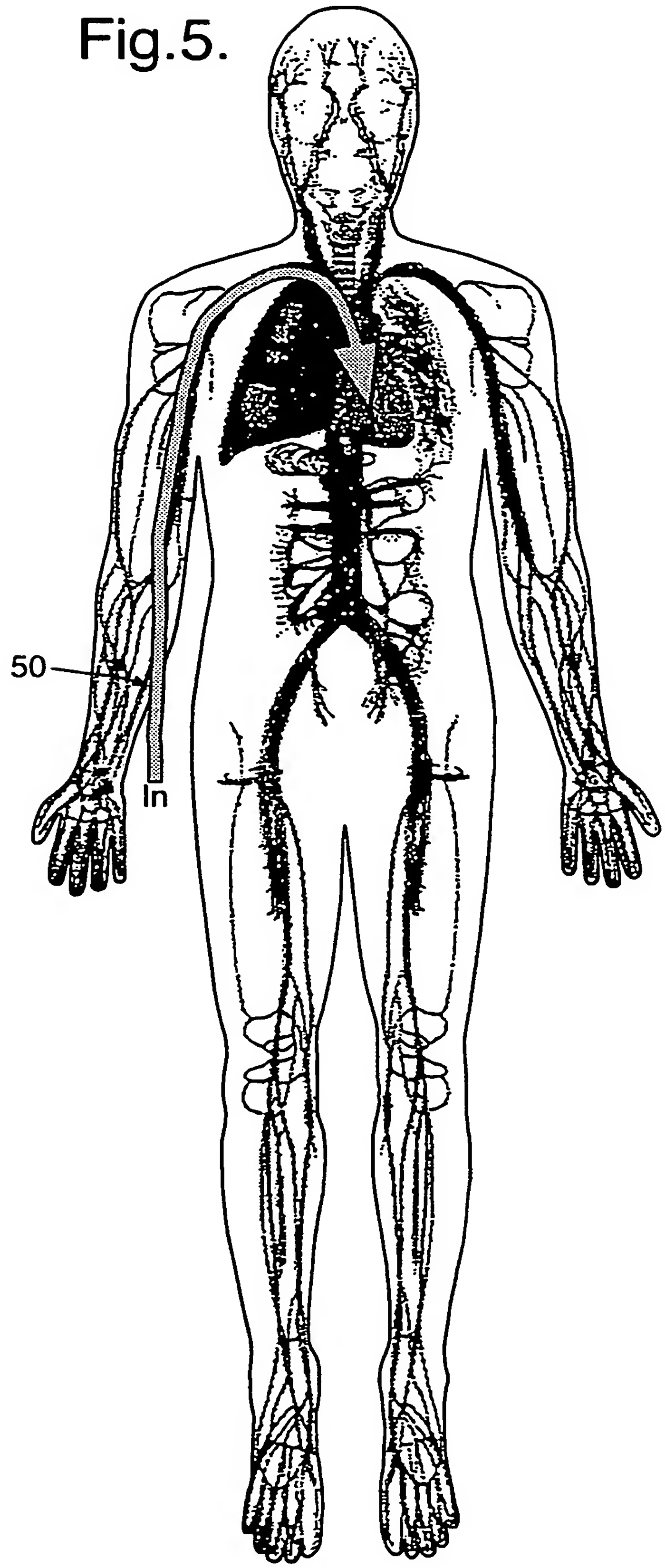


Fig.6.

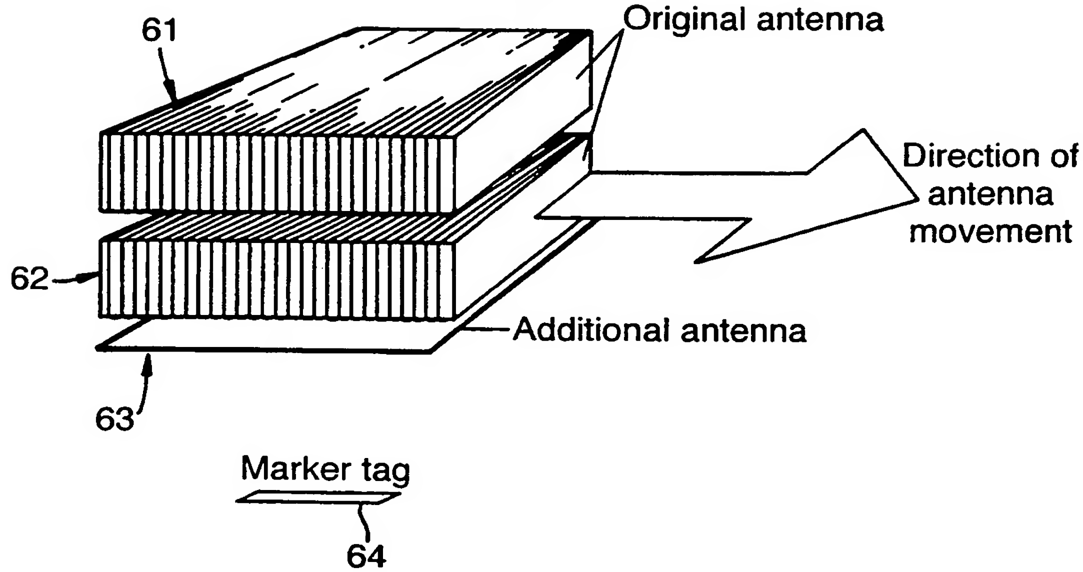
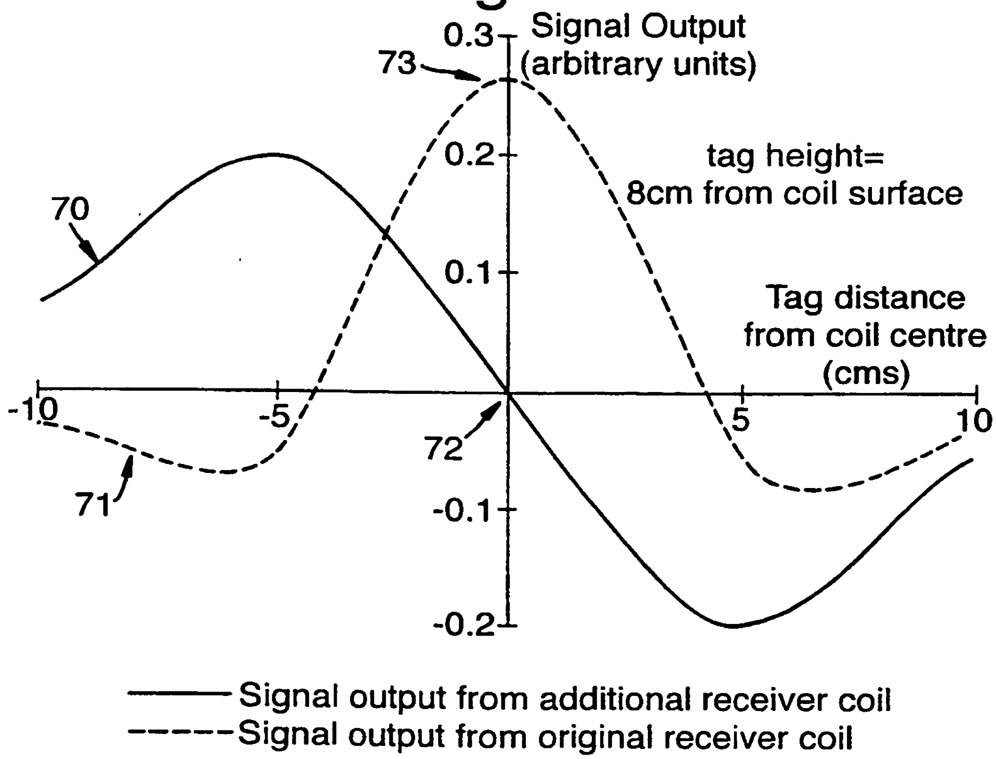

61
Original antenna
Direction of antenna movement
62
Additional antenna
63
Marker tag
64

Fig.7.


0.3
Signal Output (arbitrary units)
73
0.2
tag height= 8cm from coil surface
70
0.1
Tag distance from coil centre (cms)
-10
-5
5
10
72
71
-0.1
-0.2
Signal output from additional receiver coil
Signal output from original receiver coil

INTERNATIONAL SEARCH REPORT

International Application No
PCT/GB 98/02479

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 G01V15/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 G01V G08B A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 96 31790 A (DAMES ANDREW NICHOLAS ;SCIENT GENERICS LTD (GB)) 10 October 1996 cited in the application see abstract; claims 4,9; figure 10 see page 6, line 31 - page 7, line 36 see page 11, line 19 - page 12, line 11 see page 14, line 18 - page 15, line 12 see page 22, line 19 - page 23, line 10 see page 29, line 11 - line 22 see page 33, line 29 - line 35 see page 34, line 14 - page 35, line 1 ---	1-12
X	EP 0 320 623 A (MERTEN KG PULSOTRONIC) 21 June 1989 see abstract; claims 1,4,8; figures 1,3-5,8,9 see column 3, line 45 - column 4, line 2 ---	1-5,7,8
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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
10 December 1998	21/12/1998

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 320 100 A (HERWECK STEVE A ET AL) 14 June 1994 see abstract	1,6
X	EP 0 754 954 A (MARCONI GEC LTD) 22 January 1997	1-3
A	see abstract; figures 1,2 see column 1, line 27 - column 3, line 45	10-12
X	US 5 425 367 A (SHAPIRO ALAN R ET AL) 20 June 1995	1-4
A	see abstract; figures 1,2,5 see column 2, line 19 - column 3, line 40	6-10
A	COUDERCHON G ET AL: "PRINCIPLES OF A MAGNETIC METHOD FOR LABELLING MOVING ITEMS" IEEE TRANSACTIONS ON MAGNETICS, vol. 17, no. 6, 1 November 1981, pages 2988-2990, XP002008885 see the whole document	1,7,8

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INTERNATIONAL SEARCH REPORT

Information on patent family members

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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9631790 A	10-10-1996	AU 5280696 A	23-10-1996
		BR 9604784 A	07-07-1998
		CA 2217762 A	10-10-1996
		CN 1185210 A	17-06-1998
		CZ 9703141 A	14-01-1998
		EP 0834091 A	08-04-1998
		GB 2313745 A	03-12-1997
		GB 2322769 A	02-09-1998
		GB 2322770 A	02-09-1998
		GB 2322048 A	12-08-1998
		GB 2322049 A	12-08-1998
		NO 974587 A	04-12-1997
		PL 322617 A	02-02-1998
EP 0320623 A	21-06-1989	DE 3742298 A	22-06-1989
US 5320100 A	14-06-1994	AU 676666 B	20-03-1997
		AU 2656292 A	27-04-1993
		CA 2119252 A	01-04-1993
		EP 0604546 A	06-07-1994
		JP 7501956 T	02-03-1995
		WO 9305730 A	01-04-1993
EP 0754954 A	22-01-1997	US 5735795 A	07-04-1998
US 5425367 A	20-06-1995	AU 666672 B	22-02-1996
		AU 2511592 A	05-04-1993
		CA 2116970 A	18-03-1993
		EP 0606253 A	20-07-1994
		JP 7500979 T	02-02-1995
		WO 9304628 A	18-03-1993
		US 5645065 A	08-07-1997

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(71) Applicant *(for all designated States except US)*: FLYING NULL LIMITED [GB/GB]; Harston Mill, Harston, Cambridge CB2 5NH (GB).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: ENGLAND, Mark [GB/GB]; 44a Bitt Lane, Milton, Cambridge CB4 6DG (GB). DAMES, Andrew, Nicholas [GB/GB]; 74 De Freville Avenue, Cambridge CB4 1HU (GB). CROSSFIELD, Michael, David [GB/GB]; Perne Drift, Burton End, West Wickham, Cambridge CB1 6SD (GB).

(74) Agent: ABRAMS, Michael, John; Haseltine Lake & Co., Imperial House, 15–19 Kingsway, London WC2B 6UD (GB).

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(54) Title: IMPROVEMENTS RELATING TO SURGICAL DEVICES AND THEIR LOCATION

(57) Abstract

A surgical device, e.g. a catheter or a prosthesis, is disclosed which is characterized in that it carries, at a predetermined location, a tag formed of a high permeability, low coercivity magnetic material. Also disclosed is a method of locating a surgical device within the human or animal body, which comprises inserting the device into the body together with a magnetically active marker, the marker being associated with a predetermined location on the surgical device; and sensing the position of the marker, and hence of the surgical device, by remotely detecting its magnetic response to an interrogating signal. Systems for use in this method are also disclosed.

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AMENDED CLAIMS
[received by the International Bureau on 22 February 1999 (22.02.99);
new claim 13 added; remaining claims unchanged (1 page)]

13. A system for use in determining the location of a surgical device within the human or animal body, which system comprises:

(i) a surgical device which carries, at a predetermined location, a tag formed of (a) a high permeability, low coercivity magnetic material; and (b) a magnetised bias element positioned in proximity to and so as to couple magnetically with said magnetic material;

(ii) means for generating a rotating magnetic field; and

(iii) means for detecting the interaction between the tag and the magnetic field.

14. A system as claimed in claim 13, wherein said means for generating a rotating magnetic field comprises a pair of orthogonally arranged solenoids which function as transmit coils.